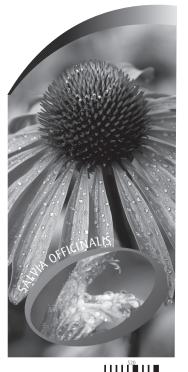


Patient Information Leaflet



Echinaforce® Sore Throat Spray Echinacea & Sage extracts



Important things you need to know

Information

- This product is used to relieve sore throats.
- Don't take this product if you are allergic to any of the ingredients: see section 6.
- Before you take this product: read section 2.
- **Dosage instructions**: see section 3.
- Talk to your doctor if your symptoms worsen or do not improve within 7 days.
- Side effects can occur when using this product: see section 4.

Now read the rest of this leaflet carefully. Keep this leaflet. You may need to read it again.

1. What this product is for

Echinaforce Sore Throat Spray is a traditional herbal medicinal product used to relieve sore throats associated with coughs, colds and flu. This is based on traditional use only.

Do's & Don'ts

2. Before you use this product

Do not take this product

- If you are under 18 years of age.
- If you are **allergic** to
 - Echinacea or plants of the daisy (Asteraceae/ Compositae) family.
 Echinacea is a member of the daisy family.
 - Sage
 - Peanut or soya. This product contains soy lecithin.
 - Any of the other ingredients in this product (see section 6 Further Information)
- If you have a tendency to allergies such as hives, allergic eczema or asthma.
- If you are pregnant or breastfeeding.
- If you are taking ciclosporin or methotrexate, or any other immunosuppressant medicine.
- If you are taking another medicine which is affected by alcohol

- If you **suffer** from
 - TB (the infection tuberculosis)
 - Sarcoidosis (a connective tissue disease disorder which causes the formation of clumps of cells mainly in the lymph nodes, lungs and liver)
 - An autoimmune disease such as collagenoses (inflammation of the connective tissue) or multiple sclerosis
 - HIV, AIDS or any other condition which decreases your resistance to infection
 - A disorder which affects your white blood cells such as agranulocytosis (low white blood cell count due to bone marrow disorders) or leukemia (blood cell cancer)
- If you are having treatment to reduce the response of your immune system (immunosuppression) e.g. chemotherapy, radiotherapy.
- If you have had an organ or bone marrow transplant.
- If you are unsure if this product is suitable for you please speak to your pharmacist or our helpline on 0845 608 5858.

See your doctor first

- If you have problems swallowing or breathing.
- If your sore throat is severe and you have a high temperature (fever), headache or if you feel sick or are being sick.
- If you have been told by your doctor that you have an intolerance to some sugars. This product may not be suitable for you.

You should also know

- This medicinal product contains 38 - 42 vol % ethanol (alcohol), i.e. up to 163 mg per 2 sprays, equivalent to 3.7 ml beer (less than a teaspoon) or 1.5 ml wine (less than half a teaspoon) per dose.
- If you suffer from alcoholism the alcohol content of this product may be harmful.
- If you are in a high-risk group (patients with liver disease or epilepsy) you should consider the alcohol content before taking this product.



Using

Remove the cap from the bottle and fit the nozzle onto the cap. Replace the cap gently but firmly onto the bottle, taking care to point the nozzle away from you. Before using this product for the first time press the pump 2-3 times to activate the spray.

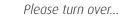


To use the spray shake the bottle well, place the nozzle just inside your mouth and point it towards the back of your throat. Press the pump to spray.



After use, turn the nozzle back down.





Using

Dosage

Shake well before use

Adults and the elderly: 2 sprays six to ten times daily.

Not for use in children or those under 18.

Do not take more than the recommended dose

Avoid getting this product in your eves. If you accidentally spray into the eyes, rinse thoroughly with water.

If you take too much

- If you take too much and feel ill, talk to your doctor. Taking too much is unlikely to be harmful.
- Overdose of this product may result in alcohol intoxication and should be treated accordingly (see section 2 You should also know).

If you forget to take this product

• Don't worry about the missed dose. Take the next dose as usual.

If you feel this product isn't working

Stop taking this product and see your doctor.

 If your symptoms worsen or if you don't feel an improvement within 7 days

Driving and using machines

• This product contains alcohol (see section 2 'You should also know' for alcohol content).

Side effects

4. Possible side effects

Like all medicines, this product can cause side effects, although not everybody gets them.

Side effects

Allergic reactions

If you already suffer from allergies you may be more likely to get them. Allergic reactions which may occur are:

Common

- Rash inside the mouth
- Burning sensation in the throat

Stop taking this product if these occur.

Frequency not known

- Skin rash
- Red, itchy skin (hives)
- Swelling of the skin due to fluid (angioedema) or swelling of the face (Quincke's oedema)
- Blistering of the skin and mucous membranes (Stevens-Johnson syndrome)
- Difficulty in breathing (bronchospasm with obstruction)
- Asthma or anaphylactic shock (a life-threatening allergic reaction)

Stop taking this product immediately if any of these occur. Seek medical advice and take this leaflet with you.

There have been isolated reports suggesting an association between Echinacea products and autoimmune diseases such as:

- Inflammation of the brain and spinal cord (disseminated encephalitis)
- Painful lumps on the shins (ervthema nodosum)
- Low blood platelet count (immunothrombocytopenia)
- Destruction of blood cells by antibodies (Evans Syndrome)
- Drvness in the mouth and eves with renal tubular dysfunction (Sjögren Syndrome)

A decrease in the number of white blood cells (leucopenia) may occur in long-term use (more than 8 weeks).

The frequency is not known. This means it is not known how often these reactions occur as there have not been enough reports to allow this information to be calculated.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Information

5. How to store this product

- Keep out of the reach and sight of children
- Do not use this product after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- Use within 2 months of opening.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. It should be a clear liquid that is brown to yellow-green in colour.

6. Further Information

What this product contains

1 ml of spray contains the tinctures of Fresh Echinacea herb 863.3 mg (Echinacea purpurea (L.)) (1:12–13) Extraction solvent: ethanol 65% V/V

Fresh Echinacea root 45.5 mg (Echinacea purpurea (L.)) (1:11–12) Extraction solvent: ethanol 65% V/V

Fresh Sage leaves 430.0 mg (Salvia officinalis L.) (1:17–18) Extraction solvent: ethanol 68% V/V

The other ingredients in the spray are sucrose laurate, soy lecithin, ethanol, peppermint oil and sorbitol liquid.

What this product looks like and the contents of the pack

Echinaforce Sore Throat Spray is a clear liquid that is brown to yellow-green in colour. It is available in 30 ml bottles.

Traditional Herbal Registration Holder and Manufacturer

Traditional Registration Holder and Batch Release:

Bioforce (UK) Ltd. 2 Brewster Place, Irvine, Ayrshire, UK KA11 5DD

Manufacturer:

Bioforce AG, CH-9325, Roggwil Switzerland

THR No. 13668/0026



This leaflet was approved on 11/2011

Echinacea is a plant which is native to America. The herb and root extracts of the Echinacea species, Echinacea *purpurea*, are combined for use in Echinaforce Sore Throat Spray.

What is Sage?

Sage is a flowering plant which is native to the Mediterranean. It is the extract of Sage leaves which is used in Echinaforce Sore Throat Spray.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

Email: enguiries@avogel.co.uk Phone: 0845 608 5858

You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your doctor's surgery or pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday-Friday).

You can get a larger print or audio version of this leaflet. Call this number: 0845 608 5858.

Certification Mark

What is Echinacea?